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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,853	10/17/2007	Katsumi Aoyagi	053466-416	4864

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/577,853	AOYAGI ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Appendix- Translations from WO 99/06836 .

DETAILED ACTION

REQUIREMENT FOR UNITY OF INVENTION

As provided in 37 CFR 1.475(a), a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in a national stage application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim. See 37 CFR 1.475(e).

When Claims Are Directed to Multiple Categories of Inventions:

As provided in 37 CFR 1.475(b), a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

Otherwise, unity of invention might not be present. See 37 CFR 1.475(c).

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, drawn to methods for the treatment of HCV-containing samples with an acidifying agent and an additional agent.

Group II, claim(s) 13-21, drawn to kits comprising an acidifying agent and an additional agent.

Group III, claim(s) 22 and 23, drawn to a hybridoma cell and a monoclonal antibody produced by such a cell.

2. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: There common technical feature among the groups are methods of detecting HCV antigens, including the antibodies used in such detection methods.

WO 94/13700 teaches one of the claimed antibodies for the detection of HCV (the oT3 antibody, see e.g., page 34). Further, the common technical feature of Groups I and II is the use of both an acidifying agent and a structurally described second agent to treat an HCV containing sample for use in a detection assay. Such a method is suggested by WO 99/06836. See e.g., abstract (teaching the use of each of the compounds to treat virus containing samples). See also, claims 1 and 4, and the first paragraph of the "Disclosure of the Invention" section of the specification (first paragraph of page 6 of the WO reference- translations attached in the appendix to this action).

Species Election

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

For Each of Groups I and II, if elected, Applicant is required to elect one of the acidifying agents of claims 5 or 16.

For Group I, if elected, Applicant is additionally required to elect one or a combination of the following:

(a) a protein denaturing agent (claims 1-3, and 8),

(b) an amphoteric surfactant (claims 1, 2, and 6),

(c) a cationic surfactant (claims 1, 2, and 7),

(d) a monosaccharide or disaccharide (claims 2 and 11),

(e) a citric acid (claims 2 and 12),

(f) a non-ionic surfactant (claims 2, 3, and 9), and/or

(g) a reducing agent (claims 2, 3, and 10).

If (b) is elected, one (or a combination) of the species of claim 6 must also be elected,

If (c) is elected, one (or a combination) of the species of claim 7 must also be elected.

If (d) is elected, one (or a combination) of the species of claim 11 must also be elected.

If (e) is elected, one (or a combination) of the species of claim 12 must also be elected.

If (f) is elected, one (or a combination) of the species of claim 9 must also be elected.

If (g) is elected, one (or a combination) of the species of claim 10 must also be elected.

For Group II, if elected, Applicant is additionally required to elect one or a combination of the following:

(a) a protein denaturing agent (claims 13-15, and 19),

(b) an amphoteric surfactant (claims 13, 14, and 17),

(c) a cationic surfactant (claims 13, 14, and 18),

(f) a non-ionic surfactant (claims 14, 15, and 20), and/or

(g) a reducing agent (claims 14, 15, and 21).

If (b) is elected, one (or a combination) of the species of claim 17 must also be elected,

If (c) is elected, one (or a combination) of the species of claim 18 must also be elected.

If (f) is elected, one (or a combination) of the species of claim 20 must also be elected.

If (g) is elected, one (or a combination) of the species of claim 21 must also be elected.

For Group III, the Applicant is required to elect one of the antibodies of HC11-9, HC11-21, or OT3 (each found in both of claims 22 and 23).

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify

the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species as indicated in the listing above. The following claim(s) are generic: claims 1-4, 13-15, 22, and 23.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the species lack unity for the same reasons as indicated with respect to the inventive groups above.

Conclusion

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648

OFFICE ACTION APPENDIX

Translation of claims 1 and 4 of WO 99/06836.

Claim 1. A method for treating a virus-containing sample, characterized by treatment of a virus-containing sample with a treatment solution containing (i) an anionic surfactant and (2) an amphoteric surfactant, a nonionic surfactant, or a protein denaturant.

Claim 4. A method according to any one of claims 1 to 4 wherein said treatment solution further contains urea, an imidazole ring-containing compound, or an indole ring-containing compound.

First paragraph of the "Disclosure of the Invention "section of the WO 99/06836 specification (first paragraph of page 6 of the reference).

It is an object of the present invention to provide a method for detecting various virus antigens, including a method for detecting HCV antigen that is suitable for treating a large number of samples as in screening in the blood industry and health checkups. In other words, the object of the present invention is to provide the detection system for various virus antigens including a method of detecting HCV antigen that has a sensitivity and specificity equivalent to those of the PCR method, that permit simple pretreatment, or that can be easily automated without pretreatment. Preferred embodiments of the present invention will now be explained hereinbelow with a main reference to HCV.